

Application No. 10/802,282

NOV 27 2006

Reply to Office Action

REMARKS/ARGUMENTS*Status of the Claims*

Claims 1-65 are pending. Claims 1, 19, 22, 23, 24 and 51 are amended herein. No new matter is added by way of these amendments.

Discussion of Section 112 Rejections

Claims 1-4, 6-18, 22, 51-54, and 56-65 are rejected under 35 U.S.C. §112 for allegedly failing to comply with the written description requirement. Applicants traverse. The Office action states that the term "acid" is not disclosed in the specification as filed. However, attention is drawn to paragraphs 17 and 27, which disclose that "Optionally, citric acid can be replaced in the lyophilized azithromycin formulation with the functionally equivalent amount of any appropriate acid (e.g. hydrochloric acid, lactic acid, glycolic acid, acetic acid, phosphoric acid, tartaric acid, or other acid)." Clearly, the term "acid" encompasses at least the acids exemplified in the specification. Therefore, Applicants submit that the written description requirement is satisfied in the instant claims and respectfully request that the rejection be withdrawn.

Discussion of Section 103 Rejections

Claims 1-65 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over 70-5191-00-8 (Pfizer Labs, Division of Pfizer Inc., NY, NY 10017 (October 2003)) referred to "Zithromax" in view of U.S. Patent No. 6,365,574 (Singer). Applicants traverse.

Zithromax discloses a lyophilized formulation containing azithromycin dihydrate. There is no teaching in Zithromax of an azithromycin formulation containing ethanol, as recited in the pending claims. The Singer patent teaches an ethanolate of azithromycin with an ethanol content of from 1.5-3 wt %. Singer does not disclose a lyophilized formulation of azithromycin much less any azithromycin formulation containing ethanol in an amount of about 0.005 % to about 0.5 % by weight as recited by the pending claims.

There is no motivation to use the ethanolate form of azithromycin as described in Singer in the lyophilized formulation described in Zithromax. One of ordinary skill would not believe that the ethanolate form of azithromycin of Singer could be successfully used to

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produce a lyophilized pharmaceutical formulation. As conditions for successful lyophilization vary widely from compound to compound and even among different forms of the same active ingredient (e.g., hydrate v. solvate), the alleged teaching that a dihydrate form of azithromycin can be lyophilized would not have led one of skill in the art to believe that an ethanolate of azithromycin could be successfully lyophilized. Obviousness to try is not the legal standard for obviousness.

Moreover, even if the cited references are combined, the lyophilized azithromycin formulations of the present invention would not be produced. Specifically, such hypothetical formulations would not have an ethanol content of about 0.005 % to about 0.5 % by weight as required by the pending claims. This ethanol content is $1/6^{\text{th}}$ and $1/3^{\text{rd}}$ of the maximum and minimum ethanol content, respectively, described in Singer. Thus, the ethanol content of the formulations of the present claims is significantly less than the ethanol content of the ethanolate form of zithromycin in Singer.

Furthermore, there no teaching or suggestion in either the Zithromax or Singer of a method for producing a stable, sterile pharmaceutical formulation comprising lyophilized azithromycin as recited in pending claims 23-50. Neither Zithromax nor Singer describe the conditions under which a lyophilized formulation of azithromycin is produced including, for example, the primary drying temperature and time and the secondary drying temperature and time. As noted above, the conditions for successful lyophilization vary widely for each active ingredient and even different forms of an active. Therefore, in view of the limited teachings of the cited references, it would not have been obvious in view of the cited references to produce a lyophilized azithromycin under the specific conditions recited in pending method claims 23-50.

In sum, there is no motivation to combine the cited references Zithromax and Singer reference and, moreover, their combination does not result in the invention of pending claims 1-65, Applicants request that the obviousness rejection be withdrawn.

Conclusion

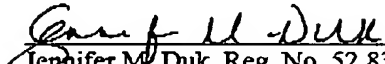
Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the

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prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,


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